AO 120 (Rev. 2/99)

TO:

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SOLICITOR
OCT 14 2009
U.S. PATENT & TRADEMARK OFFICE

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Colorado on the following Patents

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
09-02392-CMA	10/7/09	FOR THE DISTRICT OF COLORADO

PLAINTIFF	DEFENDANT
Pfizer Inc. Et al	Sandoz Inc.

	PATENT OR	DATE OF PATENT	HOLDER OF PATENT OR TRADEMARK
1	6,455,574		Please see copy of Complaint attached hereto
2			
3			
4			
5			

In the above—entitled case, the following patent(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
GREGORY C. LANGHAM		

Copy 1—Upon initiation of action, mail this copy to Commissioner **Copy 3—Upon termination of action, mail this copy to**
Copy 2—Upon filing document adding patent(s), mail this copy to Commissioner **Copy 4—Case file copy**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

PFIZER INC.,
PFIZER PHARMACEUTICALS, LLC,
PFIZER IRELAND PHARMACEUTICALS,
PFIZER LIMITED, and
C.P. PHARMACEUTICALS INTERNATIONAL C.V.,

Plaintiff,

v.

SANDOZ INC.,

Defendant.

COMPLAINT

Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Ireland Pharmaceuticals, Pfizer Limited, and C.P. Pharmaceuticals International C.V. (collectively referred to as "Pfizer"), by their attorneys, for their complaint against Sandoz Inc. ("Sandoz"), allege as follows:

1. This is an action by Pfizer against Sandoz for infringement of United States Patent No. 6,455,574 ("the '574 patent"). A copy of the '574 patent is attached hereto as Exhibit A.

2. On September 24, 2002, the United States Patent and Trademark Office issued the '574 patent, entitled "Therapeutic Combination," on an application filed by Jan Buch and assigned to Pfizer Inc.

PARTIES, JURISDICTION AND VENUE

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the assignee of the '574 patent.

4. Pfizer Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 235 East 42nd Street, New York, New York 10017. Pfizer Pharmaceuticals, LLC is a wholly owned subsidiary of Pfizer Inc.

5. Pfizer Limited is a company incorporated under the laws of England with offices at Ramsgate Road, Sandwich, Kent, England CT13 9NJ. Pfizer Limited is a wholly owned, indirect subsidiary of Pfizer Inc.

6. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

7. Pfizer Limited and Pfizer Ireland Pharmaceuticals are beneficial owners of the '574 patent.

8. C.P. Pharmaceuticals International C.V. is a limited partnership (commanditaire vennootschap) organized under the laws of the Netherlands, having its registered seat in Rotterdam, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 24280998. C.P. Pharmaceuticals International C.V. is a wholly owned subsidiary of Pfizer Inc. and the exclusive licensee of Pfizer Limited under the '574 patent.

9. C.P. Pharmaceuticals International C.V. is the owner of approved New Drug Application ("NDA") No. 21-540 for formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including 5mg/80mg and 10mg/80mg strengths. Pfizer sells drug products under NDA 21-540 in the United States under the registered name Caduet®.

10. The exclusive licensee of the '574 patent is Pfizer Pharmaceuticals, LLC by assignment from C.P. Pharmaceuticals International C.V.

11. Pfizer has all the right, title, and interest in the '574 patent and the right to sue for infringement thereof.

12. The '574 patent is identified pursuant to 21 U.S.C. § 355(b)(1) and (j)(7) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Caduet® products.

13. Sandoz is a corporation organized and existing under the laws of the State of Colorado, and has a place of business located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

14. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

15. Sandoz is subject to personal jurisdiction in this District because Sandoz is incorporated in Colorado, and resides and is found in Colorado at least for purposes of service of process.

16. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(b) and (c) and 1400(b).

CLAIM FOR RELIEF:
INFRINGEMENT OF THE '574 PATENT

17. Pfizer realleges paragraphs 1 through 16 above as if fully set forth herein.

18. Pfizer has received a letter dated August 24, 2009 (the "ANDA Notice Letter") notifying Pfizer that Sandoz had filed Abbreviated New Drug Application ("ANDA") No. 91-462 ("Sandoz's ANDA") seeking approval from the FDA to engage in the commercial manufacture, use, and sale of products containing amlodipine besylate and atorvastatin calcium, 5mg/80mg and 10mg/80mg, as the active ingredients ("Sandoz's ANDA Products") prior to the expiration of the '574 patent. A copy of the ANDA Notice Letter is attached hereto as Exhibit B.

19. The ANDA Notice Letter purported to contain an "Offer of Confidential Access" to "[a] copy of the relevant sections of the ANDA, as determined by Sandoz" pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

20. The purported "Offer of Confidential Access" contained restrictions on the access and use of the information not contemplated or permitted by 21 U.S.C. § 355(j)(5)(C)(i)(III).

21. The ANDA Notice Letter addressed the '574 patent and asserted that the patent was invalid.

22. The ANDA Notice Letter did not provide any explanation of why the claims of the '574 patent are not infringed, as would be required by 21 CFR § 314.95(c)(6)(i) if Sandoz contended that the claims were not infringed.

23. The expiration date for the '574 patent is August 11, 2018.

24. Sandoz has infringed the '574 patent under 35 U.S.C. § 271(e)(2) by filing Sandoz's ANDA seeking approval from the FDA to engage in the commercial manufacture, use,

or sale of products containing amlodipine besylate and atorvastatin calcium as the active ingredients prior to the expiration of the '574 patent.

25. Pfizer will be irreparably harmed if Sandoz is not enjoined from infringing the '574 patent.

WHEREFORE, Pfizer requests the following relief:

A. A judgment providing that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval for Sandoz's ANDA be no earlier than August 11, 2018, the date of expiration of the '574 patent;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, from making, using, selling, offering to sell, or importing Sandoz's ANDA Products until August 11, 2018, the expiration date of the '574 patent;

C. Costs and expenses in this action; and

D. Such further and other relief as this Court may deem just and proper.

Dated: October 7, 2009

Respectfully submitted,

s/ Diane J. Hellwig

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